

PMUSA Clinical Evaluation Clinical Process:

Destruction of unused study cigarettes at MDSPS investigative sites

Issue Date and Number: 24 March, 2004 (1)

The investigative site Pharmacy will pull one unopened carton of each study cigarette from the first shipment and store this at the site (under conditions per protocol) until PMUSA reviews the final CSR.

For Confinement Periods:

1. At the end of each 24-h interval, after reconciling in the ClinQuick™ system dispensed cigarettes vs. returned butts for each subject, the investigative site Pharmacy may destroy any unused loose cigarettes for that 24-h interval according to the site's Standard Operating Procedure for drug destruction and complete a Certificate of Destruction.

For Ambulatory Periods:

1. At each subject visit, after documenting in the EP-90™ system the number of full cigarette packs dispensed and the number of empty and partially full cigarette packs returned, the investigative site Pharmacy may destroy any empty cigarette packs and complete a Certificate of Destruction.

After PMUSA reviews the draft clinical study report*, the investigative site Pharmacy may destroy any unused study cigarettes according to the site's Standard Operating Procedure for drug destruction if:

- the site Pharmacy close-out monitoring report (study cigarette accountability) is completed.
- the study Monitor verifies reconciliation between the number of cigarettes (or empty packs) listed in the Certificate of Destruction and the corresponding number of unused cigarettes (or empty packs) and provides written authorization for destruction of unused study cigarettes.
- the PMUSA Study Manager has reviewed the Pharmacy close-out monitoring report, has no queries, and provides written authorization (e-mail is adequate) to the site for destruction of unused study cigarettes.

**In exceptional circumstances, with consent of PMUSA, an investigative site may destroy after statistical database lock occurs any unused study cigarettes according to the site's Standard Operating Procedure for drug destruction.*

N.B.: Each conventional carton contains 10 packs; each conventional pack contains 20 cigarettes. Deviations from this will be noted.